

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

**Food and Drug Administration/Small Business Town Meeting for
Pharmaceutical Industry**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public town meeting.

SUMMARY: The Food and Drug Administration (FDA) (Center for Drug Evaluation and Research and the Central Region and Philadelphia District) is announcing a town meeting for small businesses on FDA requirements for approval and marketing of drug products. Topics for discussion include: Over-the-counter (OTC) monographs, labeling, registration, listing, FDA meetings process, imports and exports, financial incentives, and navigating the FDA Web site. This half day meeting targets small pharmaceutical concerns.

Date and Time: The town meeting will be held on Wednesday, March 5, 2003, from 12 noon to 4 p.m.

Location: The town meeting will be held at the William J. Green Federal Bldg., conference rooms A and B, 2d floor, Sixth and Arch St., Philadelphia, PA.

Contact: Marie Falcone, Industry and Small Business Representative, Food and Drug Administration, Central Region, room 900 U.S. Customhouse, 200 Chestnut St., Philadelphia, PA 19106, 215-597-2120, ext. 4003, FAX 215-597-5798, or e-mail: mfalcone@ora.fda.gov.

Registration: To access registration form, see <http://www.fda.gov/cder/meeting/pharmbus2003/default.html>. Send registration information (including

DmB

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Certifier A. Corbin

name, title, firm name, address, telephone, and fax number) to Marie Falcone by February 14, 2003.

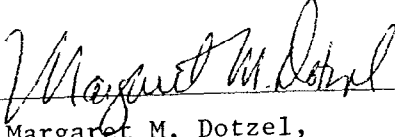
There is no registration fee, however, space is limited, therefore interested parties are encouraged to register early. Registration will close after the meeting slots are filled. Those accepted into the course will receive written confirmation. Registration at the site will be done on a space available basis on the day of the town meeting, beginning at 11 a.m. Please arrive early to ensure prompt registration. Bring photo identification for security check at building entrance. If you need special accommodations due to a disability, please contact Marie Falcone at least 7 days in advance of the workshop.

SUPPLEMENTARY INFORMATION: The “FDA Small Business Town Meeting for Pharmaceutical Industry” town meeting helps fulfill the Department of Health and Human Services’ and FDA’s important mission to protect the public health by educating regulated industry on FDA requirements to produce safe and effective drug products. FDA has made assurance of safe and effective drug products a high priority.

The workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

Dated: 1-28-03

January 28, 2003.



Margaret M. Dotzel,
Assistant Commissioner for Policy.

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